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KENNETH J. DOW
(Name of applicant, assignee, or Registered Representative

/ Kenneth J. Dow /
(Signature)

AUGUST 15, 2006
(Date of Signature)

DOCKET NO. CEN249

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: JILL GILES-KOMAR ET AL

Serial No.: 09/920,267 Art Unit: 1644

Filed : August 1, 2001 Examiner: Haddad, Maher M

For : ANTI-INTEGRIN ANTIBODIES, COMPOSITIONS, METHODS AND USES

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION FOR EXTENSION OF TIME
AND AUTHORIZATION TO CHARGE
DEPOSIT ACCOUNT THEREFOR

Dear Sir:

Applicant(s) petition(s) the Commissioner of Patents and Trademarks to extend the time for response to the Office Action dated July 6, 2006 for one(1) month(s) from August 6, 2006 to September 6, 2006. An Amendment responding to the aforesaid Office Action is being filed concurrently herewith.

Please charge Deposit Account No. 10-0750/CEN249/KD in the name of Johnson & Johnson for the cost of filing this Petition. Three copies of this Petition are enclosed.

Respectfully submitted,

/ Kenneth J. Dow /

KENNETH J. DOW
Reg. No. 32,890
Attorney for Applicant(s)

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(610)651-7422
DATE: AUGUST 15, 2006

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Docket No. CEN-249

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:Jill Giles-Komar et al.
Serial No.	:09/920,267.
Filed	:August 1, 2001.
Title	:ANTI- INTEGRIN ANTIBODIES, COMPOSITIONS, METHODS AND USES
Art Unit	:1644
Examiner	: Haddad, Maher M

Honorable Commissioner of Patents
Washington, D.C. 20231

August 15, 2006

AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT

Dear Sir:

This is in response to the RESTRICTION REQUIREMENT mailed July 6, 2006 in the above referenced application.

Applicants hereby elect the subject matter of Group II, Claims 4-8, 24-28, 44-48, 64-68 and 84-88, drawn to an isolated nucleic acid encoding a monoclonal antibody which binds to anti-dual integrin, vectors, host cells, and methods of producing, for prosecution in this application. This election is made without traverse.

In addition, as to an election of species, Applicants provisionally elect the subject matter of the nucleic acid molecule encoding the antibody having the variable heavy chain sequence of SEQ. ID. No.7 and the light chain variable sequence of SEQ.ID. No 8, as recited in claim 4.

In accordance with the restriction requirement, please enter the following amendment:

Amendments to the Specification begin on page 3 of this paper.

Amendments to the Claims are reflected in the listing of claims which begin on page 5 of this paper.

Remarks/Arguments begin on page 7 of this paper.

Amendments to the Specification:

Please replace the paragraph beginning on page 5, line 17, with the following amended paragraph:

Figures 4A-D show graphs of antibody binding to ~~αVβ3~~ αVβ3 where this ligand was preincubated in doubling dilutions starting at 10 :g/mL with 50 mM EDTA in 1% BSA-HBSS (in the absence of Ca++) or with 1% BSA-HBSS (with Ca++) for 30 min, 37EC. Mixtures added to plates coated with CNTO 95, C372, c7E3 or LM609 IgG and incubated for 1 hour, 37°C. LM609 or CNTO 95 added at 20 :g/mL in appropriate buffer (+/- Ca++) for 30 min, 37°C. Plates probed with goat anti-mouse IgG Fc, HRP or goat anti-human IgG Fc, HRP.

Please replace the paragraph beginning on page 5, line 23, with the following amended paragraph:

Figures 4E-G show graphs of antibody binding to a ~~αVβ5~~ αVβ5, where this ligand was preincubated in doubling dilutions starting at 10 :g/mL with 50 mM EDTA in 1% BSA-HBSS (in the absence of Ca++) or with 1% BSA-HBSS (with Ca++) for 30 min, 37°C. Mixtures added to plates coated with CNTO 95, C372, c7E3 IgG and incubated for 1 hour, 37°C. VNR139 was added at 10 :g/mL in appropriate buffer (+/- Ca++) for 30 min, 37°C. Plates probed with goat anti-mouse IgG Fc, HRP.

Please replace the paragraph beginning at page 14, line 19 with the following amended paragraph:

Methods for engineering or humanizing non-human or human antibodies can also be used and are well known in the art. Generally, a humanized or engineered antibody has one or more amino acid residues from a source which is non-human, e.g., but not limited to mouse, rat, rabbit, non-human primate or other mammal. These human amino acid residues are often referred to as "import" residues, which are typically taken from an "import" variable, constant or other domain of a known human sequence. Known human Ig sequences are disclosed, e.g., in a number of public databases such as the NCBI database of the National Institute of Health or publications such as ~~www.ncbi.nlm.nih.gov/entrez/query.fcgi; www.atcc.org/phage/hdb.html; www.seiquest.com/; www.abcam.com/; www.antibodyresource.com/onlinecomp.html; www.public.iastate.edu/~pedro/research_tools.html; www.mgen.uni-heidelberg.de/SD/IT/IT.html; www.whfreeman.com/immunology/CH05/kuby05.htm;~~

~~www.library.thinkquest.org/12429/Immune/Antibody.html;~~
~~www.hhmi.org/grants/lectures/1996/vlab/; www.path.cam.ac.uk/~mrc7/mikeimages.html;~~
~~www.antibodyresource.com/;~~
~~mcb.harvard.edu/BioLinks/Immunology.html www.immunologylink.com/;~~
~~pathbox.wustl.edu/~hcenter/index.html; www.biotech.ufl.edu/~hcl/;~~
~~www.pebio.com/pa/340913/340913.html; www.nal.usda.gov/awic/pubs/antibody/;~~
~~www.m.chime.u.ac.jp/~yasuhito/Elisa.html; www.biodesign.com/table.asp;~~
~~www.ionet.uk/axp/faes/davies/links.html; www.biotech.ufl.edu/~fccl/protocol.html;~~
~~www.isac-net.org/sites_geo.html; eximt1.imt.uni-marburg.de/~rek/AEPStart.html;~~
~~baserv.uci.kun.nl/~jraats/links1.html; www.recab.uni-hd.de/immuno.bme.nwu.edu/;~~
~~www.mrc-cpe.cam.ac.uk/imt-doc/public/INTRO.html; www.ibt.unam.mx/vir/V_mice.html;~~
~~imgt.cnusc.fr:8104/; www.biochem.ucl.ac.uk/~martin/abs/index.html; antibody.bath.ac.uk/;~~
~~abgen.cvm.tamu.edu/lab/wwwabgen.html;~~
~~www.unizh.ch/~honegger/AHOseminar/Slide01.html; www.cryst.bbk.ac.uk/~ubcg07s/;~~
~~www.nimr.mrc.ac.uk/CC/ccaewg/ccaewg.htm;~~
~~www.path.cam.ac.uk/~mrc7/humanisation/TAHHP.html;~~
~~www.ibt.unam.mx/vir/structure/stat_aim.html; www.biosci.missouri.edu/smithgp/index.html;~~
~~www.cryst.bioc.cam.ac.uk/~fmolina/Web-pages/Pept/spottech.html;~~
~~www.jerini.de/fr_products.htm; www.patents.ibm.com/ibm.html.~~Kabat et al., Sequences of Proteins of Immunological Interest, U.S. Dept. Health (1983)~~, each entirely incorporated herein by reference~~.

Please replace the paragraph beginning at page 19, line 15, with the following amended paragraph:

In another aspect, the invention provides isolated nucleic acid molecules encoding a(n) anti-dual integrin antibody having an amino acid sequence as encoded by the nucleic acid contained in the plasmid ~~deposited as~~ designated clone C371A. ~~names~~ ~~and ATCC Deposit Nos.~~ ~~, respectively, deposited on~~ .

Please replace the paragraph beginning at page 67, line 4 with the following amended paragraph:

Determination of Ca^{++} Dependence for Binding of anti-Human ~~∀V∃3/∀V∃5~~ αVβ3/αVβ5 Mabs to Their Ligands

It is known that the presence of the cation calcium is necessary for the Mab c7E3 to bind ~~∀V∃3~~ αVβ3 and is not a requirement for binding of Mab LM609 to αVβ3 as demonstrated in Figures 4c and 4d respectively. This experiment was conducted to assess whether calcium dependence also applies to the binding characteristics of CNTO 95 or C372 for ~~∀V∃3~~ αVβ3 or ~~∀V∃5~~ αVβ5 integrins. An excess concentration of EDTA was introduced into the assay format to chelate the Ca present within the binding pocket of the integrin heterodimers and therefore, binding was assessed in the absence of the cation. It was found that CNTO 95 and C372 binding to ~~∀V∃3~~ αVβ3 is not dependent upon the presence of Ca (Figure 4a, 4b). The same is true for CNTO 95 binding to ~~∀V∃5~~ αVβ5 but not so, however, for C372 binding to ~~∀V∃5~~ αVβ5 (Figure 4e, 4f) as binding appears to be increased in the presence of Ca.

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Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claims 1-3 (canceled).

Claim 4. (previously presented) An isolated nucleic acid encoding at least one isolated mammalian anti-dual integrin antibody having at least one variable region comprising SEQ ID NO: 7 or 8.

Claim 5. (previously presented). An isolated nucleic acid vector comprising an isolated nucleic acid according to claim 4.

Claim 6. (previously presented) A prokaryotic or eukaryotic host cell comprising an isolated nucleic acid according to claim 5.

Claim 7. (previously presented) A host cell according to claim 6, wherein said host cell is at least one selected from COS-1, COS-7, HEK293, BHK21, CHO, BSC-1, Hep G2, 653, SP2/0, 293, HeLa, myeloma, or lymphoma cells, or any derivative, immortalized or transformed cell thereof.

Claim 8. (previously presented) A method for producing at least one anti-dual integrin antibody, comprising translating a nucleic acid according to claim 4 under conditions in vitro, in vivo or in situ, such that the dual integrin antibody is expressed in detectable or recoverable amounts.

Claims 9-23 (canceled)

Claim 24. (amended) An isolated nucleic acid encoding at least one isolated mammalian anti-dual integrin antibody comprising ~~either~~ (i) all of the heavy chain CDR amino acid sequences of SEQ ID NOS:1, 2, and 3; ~~or~~ and (ii) all of the light chain CDR amino acids sequences of SEQ ID NOS:4, 5, and 6.

Claim 25. (amended) An isolated nucleic acid vector comprising an isolated nucleic acid according to claim 4 24.

Claim 26. (amended) A prokaryotic or eukaryotic host cell comprising an isolated nucleic acid according to claim ~~25~~ 24.

Claim 27. (previously presented) A host cell according to claim 26, wherein said host cell is at least one selected from COS-1, COS-7, HEK293, BHK21, CHO, BSC-1, Hep G2, 653, SP2/0, 293, HeLa, myeloma, or lymphoma cells, or any derivative, immortalized or transformed cell thereof.

Claim 28. (previously presented) A method for producing at least one anti-dual integrin antibody, comprising translating a nucleic acid according to claim 24 under conditions in vitro, in vivo or in situ, such that the dual integrin antibody is expressed in detectable or recoverable amounts.

Claims 29-101. (canceled).

Claim 102 (Newly added) An isolated nucleic acid encoding a human monoclonal antibody comprising human heavy chain and human light chain variable regions comprising the amino acid sequences shown in SEQ ID NO: 7 and SEQ ID NO: 8, respectively.

Claim 103. (newly added). An isolated nucleic acid vector comprising an isolated nucleic acid according to claim 102.

Claim 104. (newy added) A prokaryotic or eukaryotic host cell comprising an isolated nucleic acid according to claim 102.

Claim 105. (newly added) A host cell according to claim 104, wherein said host cell is at least one selected from COS-1, COS-7, HEK293, BHK21, CHO, BSC-1, Hep G2, 653, SP2/0, 293, HeLa, myeloma, or lymphoma cells, or any derivative, immortalized or transformed cell thereof.

Claim 106. (newly added) A method for producing at least one anti-dual integrin antibody, comprising translating a nucleic acid according to claim 102 under conditions in vitro, in vivo or in situ, such that the dual integrin antibody is expressed in detectable or recoverable amounts.

Claim 107. (newly added) An isolated nucleic acid according to claim 102 wherein the antibody completely inhibits M21 cell adhesion to vitronectin.

Claim 108. (newly added) An isolated nucleic acid according to claim 102 wherein the antibody comprises a human IgG heavy chain and a human kappa light chain.

Claim 109. (newly added) An isolated nucleic acid according to claim 102 wherein the antibody comprises an IgG1 or IgG3 heavy chain.

Claim 110 (newly added) An isolated nucleic acid according to claim 102 wherein the antibody is an IgG1kappa antibody.

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REMARKS/ARGUMENTS

The specification has been amended to correct typographical errors and to remove the embedded hyper-links.

Claims 1-3, 9-23, and 29-101 have been canceled in accordance with the earlier restriction requirement and to narrow the issues in the case. Applicant retains the right to present claims to the cancelled subject matter in a divisional application.

Amendments have been made to claims 24-26 for clarity purposes and to correct dependencies.

New claims 102-110 have been added. Support for the new claims can be found in the specification at page 19, line 4. No new matter has been added.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

By: / Kenneth J. Dow /
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Dated: August 15, 2006